**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 2, 2015

Limacorporate S.p.A.
% Mr. Stephen Peoples
Peoples & Associates Consulting LLC
5010 Lodge Pole Lane
Fort Wayne, Indiana 46814

Re: K141934
Trade/Device Name: Physica KR knee system
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, HRY
Dated: February 25, 2015
Received: February 27, 2015

Dear Mr. Peoples:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K141934
Device Name: Physica KR knee system
Indications for Use:

# Physica KR knee system
# Indications for Use

Physica total knee system is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Inflammatory degenerative joint disease including rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of fractures that are unmanageable using other techniques.

Physica knee system is intended for cemented fixation.

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|---|---|---|
| Prescription Use X<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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# Summary of Safety and Effectiveness

Date: July 3, 2014

Manufacturer:
Limacorporate S.p.A.
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33038 – Villanova di San Daniele
Udine - Italy

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| Product | Common Name | Product Code | Regulation and Classification Name |
|---|---|---|---|
| Physica KR knee system | Total Knee System | JWH | Knee joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis per 21 CFR 888.3560 |
| | | HRY | Knee joint Femorotibial Metal/Polymer Semi-Constrained Cemented Prosthesis per 21 CFR 888.3530 |

**Description**

The Physica KR Knee Replacement System is a total knee replacement system consisting of femoral, tibial plate, tibial liner, patella, and tibial stem components; the tibial stem and patella components are optional to be used as required for each individual patient. The Physica KR knee system devices are intended to be used with bone cement.

The femoral components are made of CoCrMo alloy according to the requirements of ISO 5832-4 and ASTM F75. The articulating surface is polished and has asymmetric condyles along the sagittal plane. Conformity between the inner surface of the components and the resected bone of the distal femur and two fixation pegs provide stability. Ten (10) sizes in left and right versions are available. The tibial plates are made of Ti6Al4V alloy meeting the specifications of ISO 5832-3 and ASTM F1472. The inferior aspect of the component has a keel and an optional modular tibial stem, manufactured from Ti6Al4V alloy, provide stability. A plug manufactured from standard UHMWPE (ISO 5834-2 / ASTM F648) is used to fill the female taper hole used to attach the optional stem; the plug is removed if a stem is used. The superior portion of the tibial plate is designed to lock the tibial liner through a snap-fit mechanism; the superior surface of the plate is polished to reduce back-side wear of the liner. Ten sizes of symmetric tibial plates are available.

Liners are made of standard UHMWPE (ISO 5834-2 / ASTM F648). They are characterized by a concave medial hemi-plateau along the sagittal plane while the lateral

plateau is slightly convex. The articulating hemi-plateaus are both concave along the frontal plane. The liner is attached to the tibial plate through a snap-fit mechanism The anterior aspect of the liner is shaped to accommodate the patellar tendon during flexion-extension movements of the knee. Ten (10) sizes, correspondently to the tibial plate sizes, in six (6) thicknesses, are available in versions for left and right knees.

Tibial stems, in three (3) lengths (20, 40, and 60mm), are made of Ti6Al4V alloy (ISO 5832-3 / ASTM F1472). They stems are 15.5mm in diameter and cylindrical in shape with longitudinal grooves intended to increase the torsional stability of the device and to facilitate the distribution of the bone cement on the device during its insertion. Three lengths are available.

The all-polyethylene patella components, in six (6) diameters (26, 29, 32, 35, 38, and 41mm), are made of standard UHMWPE (ISO 5834-2 / ASTM F648). The components have a biconvex surface to articulate with the trochlear groove of the femoral component. The inferior surface has three (3) pins / pegs and a cement pocket to aid in fixation.

**Intended Use**

Physica total knee system is indicated for use in knee arthroplasty in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease: including osteoarthritis, traumatic arthritis, or avascular necrosis;
- Inflammatory degenerative joint disease including rheumatoid arthritis;
- Correction of functional deformity;
- Revision procedures where other treatments or devices have failed; and
- Treatment of fractures that are unmanageable using other techniques.

Physica knee system is intended for cemented fixation.

**Predicate Devices**

- G1 knee system (Aequos, K033260);
- Journey II CR knee system (Smith&Nephew, K121443) and Genesis II (Smith&Nephew, K951987);
- EVOLUTION MP total knee system (Wright Medical Technology, K093552).

**Basis of Substantial Equivalency**

The subject Physica KR knee system and all of the predicates are semi-constrained, fixed bearing modular knee replacement systems. The subject device and all of the predicates are of similar design and geometry and have similar indications for use such as total knee replacement for non-inflammatory arthritis such as OA and post-traumatic arthritis and inflammatory arthritis such as RA. The Wright Medical predicate also includes the

indication for use of treatment of fractures while the Smith & Nephew predicate includes the indication for use of treating failed osteotomies and failed unicompartmental and total knee replacements. The subject device as well as all of the predicates is intended to be fixed with bone cement. All of the devices are manufactured from similar materials. The Physica KR femoral components as well as the femoral components of all of the predicates are manufactured from CoCrMo alloy. All patella components are manufactured from standard ultra high molecular weight polyethylene (UHMWPE). The tibial base plate of the subject device and the Smith & Nephew Journey II predicate are manufactured from Ti6Al4V alloy while the tibial plates of the G1 and Evolution MP devices are manufactured from CoCrMo alloy. All devices have tibial liners made from standard UHMWPE while the Smith & Nephew predicate also has liners available in cross-linked UHMWPE. The subject device and the G1 have modular tibial stems: the subject device's tibial stem is manufactured from Ti6Al4V alloy while G1 predicate has tibial stems manufactured from CoCrMo alloy. The subject device tibial tray is keeled as Smith & Nephew Journey II and Wright Medical device. The subject device as well as all of the predicates has femoral and tibial liner components in left and right versions. The Physica KR device and the G1 predicate have tibial plates that can be used in either left or right knees while the Smith & Nephew and Wright Medical tibial plates are provided in left and right knee versions. All devices are available in a similar range of sizes and all devices are sterile packaged single use devices sterilized by similar methods.

**Non-Clinical Testing**

The following tests were performed on Physica KR knee system devices:

- Fatigue testing of the tibial plate;
- Wear test;
- Constraint tests at tibio-femoral and patello-femoral interfaces;
- Contact areas and pressures at tibio-femoral and patello-femoral interfaces;
- Test on the locking strength between the tibial plate and the tibial liner;
- Static shear test on the patella.

Mechanical testing was performed on worst case components or constructs. The testing results demonstrated the device's ability to perform under expected clinical conditions.

**Clinical Testing:**

Clinical testing was not necessary to demonstrate substantial equivalence of the Physica KR knee system to the predicate devices.